Michael J. Gregor

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COMPUTER SYSTEMS VALIDATION LEAD

Results-driven CSV and CSA Leader offering years in the FDA-regulated industry, specializing in supporting pharmaceutical, biologic, and medical device companies. Skilled in strategizing and implementing complex computer system validation and integration projects, overseeing the successful validation of over 50 systems, including enterprise-wide solutions such as SAP, MES, Oracle, QMS, LIMS, LMS, and clinical data management systems. Adept in adhering to FDA GMP, GCP, GDP, HIPAA, and GLP regulations, and well-versed in 21 CFR Part 11 regulations. Strong track record in establishing and executing Global CSV programs for leading organizations, driving harmonization efforts during pharmaceutical company acquisitions to achieve compliant and unified programs.

Offer a focus on the successful implementation of manufacturing and laboratory and computerized systems at multi-use sites. Proven expertise in systems validation, supervising vendors for qualification functions, and managing projects of varying scope and complexity. Skilled in developing validation/qualification deliverables and managing system implementation projects from scheduling to turnover. Exceptional ability to complete all qualification and validation documentation with accuracy, adherence to Company standards, and excellent customer service and support. Proficient in providing technical guidance on computerized systems qualification issues, fostering positive relationships with team members and site customers to promote a collaborative team environment. Seasoned expert in the CSA approach for several projects.

Professional Experience

Compliance Gurus LLC **President and CEO, 2003 – Present**

Takeda | Project Manager, CSV Lead and Technical BA, Nov 2022 – Nov 2023

Manage Change Control in the TrackWise application, author Validation Plan, System Requirements Specification, Operational Qualification, Performance Qualification, Traceability Matrix, SOPs, and Validation Summary Report for NuGenesis. Collaborate with Veeva and TrackWise. Incorporated the CSA approach for the validation of the NuGenesis application.

Blueprint Medicines | Validation Lead and Technical Writer, 2022 – 2023

Served as Validation Lead and Technical Writer for Oracle Fusion Validation and Implementation project at Blueprint Medicines. Authored Validation Plan, Risk Assessments, System Requirements Specification, Data Migration Plan, Data Migration Summary Report, and Validation Summary Report. Reviewed UAT Test Scripts and Configuration Specification. Worked with Siemens Audit, CAPA, and Change Modules. Incorporated the CSA approach for the validation of the Oracle Fusion application.

DP Clinical | CSV Lead, 2021 – 2022

Assumed the role of CSV Lead for the validation of multiple systems, including Medrio, e-TMF Trial Interactive, Ennov, Rave, Clue Points, DocuSign, Bioclinica, and CTMS. Authored all CSV SOPs to ensure compliance and efficiency. Worked with Siemens Audit, CAPA, and Change Modules. Also, validated these Modules for their Intended Use. Incorporated the CSA approach for the validation of the above-mentioned software applications. Ensured all clinical applications were compliant with GCP and HIPAA regulations.

Infrutronix | CSV Lead, 2021

Took charge as CSV Lead for the validation and implementation of JAMA Connect SolidWorks, Infuscale, and POMS MES with PLC/SCADA systems at Infrutronix. Incorporated the CSA approach for the validation of the above software applications.

DocuVault | CSV Lead, 2021

Led the CSV Lead role for the validation and implementation of QBench LIMS at DocuVault. Authored Validation Plan, Software Requirements Specification (SRS), Operational Qualification (OQ), and Validation Summary Report (VSR).

Spectrum Pharmaceuticals | CSV Expert, 2020 – 2021

Served as a CSV expert for an e-TMF Data Migration project at Spectrum Pharmaceuticals. Successfully migrated e-TMF data from NextDocs to Veeva e-TMF. Authored Data Migration Plan, PQ, and Data Migration Summary Report. Led the validation of Veeva Vault.

PMV Pharmaceutical | Senior Validation Engineer, 2020 – 2021
As a Senior Validation Engineer, played a key role in validating 4G IRT, Rave EDC, and LIMS Systems for PMV Pharmaceutical. Authored System Risk Assessments, Validation Plans, System Requirements Specifications, Test Plans, Traceability Matrices, and Validation Summary Reports.

Gilead Sciences | Senior Data Integrity Advisor, 2020
Provided expert advice to Gilead Sciences as a Senior Data Integrity Advisor. Reviewed and made suggestions to DI Policies, Standards, SOPs, Risk Assessments, Change Management Programs, and CSV Programs. Offered recommendations on FDA 483s and Warning Letters to third-party suppliers. Served as QAV expert.

AveXis/Novartis | Senior CSV Lead, 2019 – 2020
As a Senior CSV Lead, engaged in day-to-day support, change controls, and CAPAs at AveXis/Novartis. Led the Novartis/AveXis CSV Integration project called IMF (Information Management Framework). Successfully validated ERP/MRP, Compliance Wire, and WMS systems. Worked with Siemens Audit, CAPA, and Change Modules. Also, validated these Modules for their Intended Use. Accomplished all tasks remotely.

Sanofi | Global CSV Lead, 2018- 2019
Led a team of 16 Sanofi employees as Global CSV Lead. Evaluated and streamlined Global CSV SOPs and templates, resulting in a new Data Integrity Program used globally. Successfully validated POMS MES system with SCADA/PLCs, conducted a 52-page Part 11 Assessment, and validated the Bugsee crash reporting tool. Collaborated remotely with teams in Cambridge, MA, and Germany.

Archer DX | Data Integrity Program Creator, 2018
Developed and implemented a comprehensive Data Integrity Program at Archer DX, serving as the CSV Lead with six direct reports. Performed 21 CFR Part 11 assessments on Odoo (MRP/ERP) system and LIMS and validated Odoo (ERP/MRP) system, Greenlight Guru (eQMS), StarLIMS, and DLBCL Assay Software system according to the new Data Integrity program. Accomplished all tasks remotely in close collaboration with the team in Boulder, Colorado.

Abbott | SLC Initiative Lead, 2017
Served as the SLC Initiative Lead for Abbott, harmonizing the Software Lifecycle processes after Abbott's acquisition of St. Jude Medical. Conducted gap assessments of validation packages against Part 11 and GAMP 5 standards and identified discrepancies in St. Jude Medical's Software Lifecycle SOPs. Presented assessments and recommendations to senior leadership and developed a Quality Plan for Abbott's SLC integration into the St. Jude Medical process. Collaborated remotely with periodic site visits to Waukegan, IL.

Boston BioMedical | 21 CFR Part 11 Assessment, 2017
Conducted a 21 CFR Part 11 assessment of applications and the network at Boston BioMedical. Made observations and provided remediation recommendations for each system in a gap assessment report, ensuring data integrity ahead of NDA filing in November. Also, validated the clinical system called RedCAP to comply with 21 CFR Part 11 and data integrity requirements.

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The University of Chicago | Clinical System Validator, 2016
Validated the clinical system called RedCAP for compliance with 21 CFR Part 11 at the University of Chicago. Created a Validation Plan, Software Requirements Specification, and a Validation Summary Report. Additionally, served as a Project Manager to integrate clinical systems across campuses. Conducted the majority of tasks remotely with a single site visit.

Johnson Matthey | Global SAP System Validation, 2015 – 2016

Performed a full validation of Johnson Matthey's Global SAP system after creating an entire Data Integrity Program. Authored Validation Plan, Software Requirements Specification, Traceability Matrix, and Validation Summary Report. Ensured data integrity through the validation process. Conducted tasks remotely with a single site visit.

Astellas Pharmaceuticals | Global Electronic Systems QA Lead, 2013 – 2016
Led the Electronic Systems Quality Assurance (ESQA) for Project Orion at Astellas Pharmaceuticals. Architected the Data Center Relocation approach for the EU, Japan, and the US and qualified supporting infrastructure to ensure data integrity. Supported validated application projects, assessed systems of the acquired company for validation requirements, and integrated regulated systems. Collaborated remotely with teams in the EU and US.

WoundVision | Reviewed Software Validation Deliverables
Reviewed all software validation deliverables for an imaging device and assisted in authoring the 510(k) submission, software section, and CSV deliverables. Served as the project manager for all validation deliverables for the 510(k) submission. Accomplished 100% remote.

Affymetrix | Reviewed Software Validation Deliverables
Reviewed all software validation deliverables for an IVD device and assisted in authoring the 510(k) submission software section. Served as the project manager for all validation deliverables for the 510(k) submission. Accomplished 100% remote.

Digital Altitudes | Assisted with 510(k) Submission and Software Validation
Assisted with the 510(k) submission and performed software validation in accordance with 21 CFR Part 11. Served as the project manager for all validation deliverables for the 510(k) submission. Accomplished 100% remote.

SafeHeart Medical | Assisted with 510(k) Submission and Software Validation
Assisted with the 510(k) submission and performed software validation in accordance with 21 CFR Part 11. Served as the project manager for all validation deliverables for the 510(k) submission. Accomplished 100% remote.

NextHealth | Assisted with 510(k) Submission and Software Validation
Assisted with the 510(k) submission and performed software validation in accordance with 21 CFR Part 11. Served as the project manager for all validation deliverables for the 510(k) submission. Accomplished 100% remote.

SolidWorks | FDA Validation Kit Development, 2012 – 2013
Created an FDA Validation Kit for the EPDM tool developed by SolidWorks, ensuring compliance with 21 CFR Part 11. Developed all validation deliverables, including Validation Master Plan, System Requirements Specification, Traceability Matrix, Test Scripts, and Validation Summary Report. Provided computer system validation support to VARS and their clients for the EPDM tool.

Haemonetics | IT Systems Evaluation, 2012
Evaluated IT Systems and procedures after the acquisition of Pall Corporation by Haemonetics. Identified compliance gaps and recommended changes to ensure data integrity. Conducted computer system validation on various applications, trained staff on new IT procedures, and presented recommendations to Senior Management. Authored new IT procedures, including Data Privacy and Protection, Validation Lifecycle, Change Control, and 21 CFR Part 11 Assessments. Developed and implemented a comprehensive CSV/ERES program for Haemonetics.

Agile Therapeutics | Software Validation, 2012
Performed a 21 CFR Part 11 assessment of applications and the network and conducted 21 CFR Part 11 training for employees. Performed a computer system validation of the BOX application and reviewed NDA Submission SOPs. Additionally, performed Excel Spreadsheet validation.

The Dodge Company | cGMP Audit, 2012
Conducted a cGMP audit of the entire company, issued an audit report of the findings, and assisted with FDA remediation of a Warning Letter and a 483. Authored several SOPs and Batch Records. Performed a computer system validation on the Product Recall system and conducted cGMP training for all employees.

CoTherix/Roche | eMDR Software Validation, 2011 – 2012
Validated the eMDR application for 21 CFR Part 11 compliance. Authored Validation Plan, Risk Assessment, IQ, OQ, PQ, and Validation Summary Report.

Neurologix | Performed Validation for New ERP System

Performed computer system validation for a new ERP system in compliance with 21 CFR Part 11. Wrote and executed test scripts and worked with the software vendor to close validation issues.

The Dodge Company | FDA Audit Remediation
Remediated all FDA audit findings from the FDA's inspection of The Dodge Company, resulting in the FDA lifting the Warning Letter. Conducted a gap analysis and remediation plan, leading to the completion of a full CSV/ERES program in a short period.

Nuon Therapeutics | Validation for Clinical Drug Supply System
Validated the clinical drug supply system in compliance with 21 CFR Part 11. Authored Validation Plan, Risk Assessment, IQ, OQ, PQ, and Validation Summary Report.

Chiron | Assisted with 21 CFR Part 11 Compliance
Assisted Chiron with 21 CFR Part 11 compliance and reviewed their validation procedures.

Wyeth | IT Remediation Project
Remediated all IT issues for the validation of systems identified during an FDA inspection. Ensured the successful launch of the company's vaccine product.

Johnson & Johnson | Reviewed CSV SOPs
Reviewed and provided recommendations on CSV SOPs for Johnson & Johnson.

IBM | Reviewed Validation Deliverables
Reviewed and provided recommendations on validation deliverables for a global data warehouse project for IBM.

Shionogi Pharma | Assisted with System Validation
Assisted Shionogi Pharma with system validation activities, including Validation Plan, IQ, OQ, PQ, and Validation Summary Report.

Cephalon | Assisted with Computer System Validation
Assisted Cephalon with computer system validation activities, including Validation Plan, IQ, OQ, PQ, and Validation Summary Report.

Bristol-Myers Squibb | Assisted with Data Integrity Program
Assisted Bristol-Myers Squibb with the development and implementation of a comprehensive Data Integrity Program.

Biogen Idec | Reviewed Validation Processes
Reviewed validation processes and provided recommendations for improvement at Biogen Idec. Served as CSV Lead for lab systems and had 4m direct reports.

Siemens | Assisted with CSV Training
Assisted Siemens with CSV training for their validation team.

AREAS OF EXPERTISE & TECHNICAL ACUMEN

CSV Leadership | FDA Regulations | Pharmaceutical Industry | Biologic Industry | Medical Device Industry | Business Management | Information Systems | IT Strategy | Computer System Validation | Integration Projects | Enterprise-Wide Systems | SAP | MES | Oracle | QMS | LMS | Clinical Data Management Systems | GMP Regulations | GCP Regulations | GDP Regulations | GLP Regulations | 21 CFR Part 11 Regulations | Global CSV Programs | Pharmaceutical Company Acquisition | Compliance Management

Software Change Control | Risk Management | Software Hazard Analysis | Engineering Documentation | Stakeholder Collaboration | DHF Audits | Internal and External Audits | Training and Coaching | Project Management | Equipment Qualification | Systems Validation | Configuration Management | Validation Plans | Requirements Specifications | Traceability Matrices | Change Controls | Laboratory Equipment Implementation | Manufacturing Equipment Implementation | Customer Service | Technical Support | Calibration Management | Preventive Maintenance | Analytical Skills | Problem-Solving | Team Collaboration | Relationship Building

EDUCATION, PROFESSIONAL TRAINING & AFFILIATIONS

Keller Graduate School of Management, DeVry University, Chicago, IL MBA, with a concentration in Information Systems (IS)
National - Louis University, Chicago, IL Bachelor of Science, Business Management cGMP Interpretation and Application, Validation and Equipment Qualification, Network Qualification, Atomic Absorption, FDA Inspections, ISO 9000 Procedural Writing (SOPs), Electronic Batch Records, GAMP IV & V, Part 11 and Assessments, Interpretation, and Application of GMP, GLP, GCP regulations, ICH Q7a, ISO13485, ISO14971, HIPAA CHP and CHSS courses, Medical Device Law and Regulation Conference, Drug Law and Regulation Conference, Food Law and Regulation Conference, Dietary Supplement Law and Regulation Conference, LIMS

ASQ, ASQ FDC (Food, Drug, & Cosmetic Division), FDLI (Food, Drug, and Law Institute), 2009-2010 Newsletter Committee Chair for the ASQ FDC (Food, Drug, & Cosmetic Division), ISPE

PUBLICATIONS

"Is Your Compliance a Throw of the Dice? PharmaManufacturing May 2009
"What Does Use For Regulatory Purposes Really Mean?" Update January/February 2009
"Human and Veterinary Drug; cGMP Violations and Trends." PharmaManufacturing February 2009
"Computer System Validation: FDA Inspections." Life Science Leader March 2010
"FDA Violations and Industry Trends." Life Science Leader July 2010
"Software Vendor Audits." Contract Pharma June 2010
"Internal Audits." Life Science Leader August 2010
"No Nonsense Computer Systems Validation: Covering All Bases" PharmaEvolution March 26th, 2013

PRESENTATIONS

Presented at Food, Drug, and aw Institute's (FDLI) Conference on "Introduction to Drug Law and Regulation" and conducted a breakout session titled " When FDA Comes a Knocking, How to Prepare for FDA Inspections on June 25th – June 26th, 2009".
Presented at International Pharmaceutical Canada's Conference for "Internal Auditing for FDA, Canadian, and Japanese Regulations, Strategy for Systematic Internal Audit Planning, Execution and Reporting on October 2nd – October 3rd, 2008, in Montreal, Canada".
Presented at American Society for Quality, Thames Valley in Groton, CT. on "Computer System Validation: FDA Inspection" on April 30th, 2009
Presented at American Society for Quality Merrimac Valley on "Computer System Validation: FDA Inspection" on September 3rd, 2009
Presented at International Pharmaceutical Canada's Conference in Somerset, New Jersey on "Effective quality Assurance Auditing" on September 17th – 18th, 2009.
Served as Co-Chair of the FDANews "2nd Annual Supplier Quality Management Congress, Assuring the Integrity of Drug and Device Raw Materials and Supply Chain" on August 18th – 20th, 2010.
Served as Session Leader for the "Compliance and Audits" Track for the 2010 Regulatory Affairs Professionals Society (RAPS) Annual Conference and Exhibition on October 24th- 27th, 2010.